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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,514	04/26/2007	Eiichi Momotani	1349.46042X00	4749

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,514	MOMOTANI ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3 are pending and under consideration.

Specification

2. The disclosure is objected to because of the following informalities:

Page 1, line 5, what is meant by "before increase the specific antibody"?; first two sentences of "Background Art" have no verb; line 17, 'paratuberuculosis' should be 'paratuberculosis'; line 18, 'paratuberuculosis' should be 'Paratuberculosis'; line 20, 'routes of infection is' should be 'routes of infection are'.

Page 2, line 11, 'prevailed' should be 'prevalent'.

Page 3, line 2, 'diagnostic methods such' should be 'diagnostic methods of such'.

Page 6, line 11, what is meant by 'until to recognize'; line 14-15, 'from a carrier animals' should be 'from a carrier animal'.

Page 13, lines 18-22, the sentence has unclear.

Page 16, line 3, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 24, line 16, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Drawings

3. Figures 2, 3, 4, and 5 are objected to because the figures show asterisks, i.e., **, without explanation. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are

required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted steps are: 1) determining a proper dilution of anti-IL10 antibody; 2) comparison of results with control values, and; 3) determination of cutoff value which determines a positive infection.

The specification teaches that dilutions of the particular anti-IL10 antibody used should not be equal to or greater than 25600 because such dilutions do not distinguish between infected and uninfected cattle (Figure 1-7), And that even uninfected cattle show some level of interferon gamma production.

6. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for distinguishing between infected and uninfected cattle by using *M. avium* subsp. *paratuberculosis* PPD, does not reasonably provide enablement for the use of other single antigens from *M. avium* subsp. *paratuberculosis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a method for diagnosing paratuberculosis comprising adding anti-IL10 antibody and a single antigen from *M. avium* subsp. *paratuberculosis* to blood and measuring an amount of interferon-γ after culture.

The state of the prior art as evidenced by the instant specification indicates that the specific assay utilizing PPD from *M. avium* subsp. *paratuberculosis* has not been performed prior to the instant application. In addition, Koets et al (*Vet. Immunol. Immunopathol.*, 70(1-2):105-115, 1999) teach that substituting a single antigen for PPD from *M. avium* subsp. *paratuberculosis* does not result in the same reactivity utilizing samples from cattle infected with *M. avium* subsp. *paratuberculosis.* Thus, there is a lack of predictability in the art that merely substituting PPD from *M. avium* subsp. *paratuberculosis* with any single antigen from *M. avium* subsp. *paratuberculosis* would result in the ability to diagnosis infection by *M. avium* subsp. *paratuberculosis* utilizing the instant methodology.

The amount of direction or guidance present is insufficient for the broad scope of the instant claims, i.e., any single antigen from isolated *M. avium* subsp. *paratuberculosis*, in the instant inventions because the specification utilizes only PPD from *M. avium* subsp. *paratuberculosis* or concanavalin A.

Thus, the quantity of experimentation necessary to determine if any single antigen (or even combinations of single antigens) from *M. avium* subsp. *paratuberculosis* can substitute for the PPD actually utilized constitutes merely an invitation to experiment without a reasonable expectation of success.

7. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for distinguishing between *M. avium* subsp. *paratuberculosis* infected and uninfected cattle by using *M. avium* subsp. *paratuberculosis* PPD, does not reasonably provide enablement for methods of diagnosis of any/all other mycobacterial diseases and infections using only a single antigen from any/all mycobacteria. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a method for diagnosing any/all mycobacterial diseases or infections comprising adding anti-IL10 antibody and a single antigen from any/all species of *Mycobacterium* to blood and measuring an amount of interferon-γ after culture.

The state of the prior art as evidenced by the instant specification indicates that the specific assay utilizing PPD from *M. avium* subsp. *paratuberculosis* has not been performed prior to the instant application. Koets et al (*Vet. Immunol. Immunopathol.*, 70(1-2):105-115, 1999) teach that substituting a single antigen for PPD from *M. avium* subsp. *paratuberculosis* does not result in the same reactivity utilizing samples from cattle infected with *M. avium* subsp. *paratuberculosis*. Thus, there is a lack of predictability in the art that merely substituting PPD from *M. avium* subsp. *paratuberculosis* with any single antigen from *M. avium* subsp. *paratuberculosis* would result in the ability to diagnosis infection by *M. avium* subsp. *paratuberculosis* utilizing the instant methodology.

In addition, the state of the prior art as evidenced by Cole (2002), Lind (1984) and Merkal (1984) shows that antigens of all of the species of *Mycobacterium* do not always share immunological crossreactivity.

The amount of direction or guidance present is insufficient for the broad scope of the instant claims, i.e., any single antigen isolated from any species of *Mycobacterium* can be utilized in the instant methods for diagnosis of any/all other mycobacterial disease or infections inventions because the specification utilizes only PPD from *M. avium* subsp. *paratuberculosis* or concanavalin A to diagnosis infection with *M. avium* subsp. *paratuberculosis*.

Thus, the quantity of experimentation necessary to determine if any single antigen (or even combinations of single antigens) from *M. avium* subsp. *paratuberculosis* can substitute for the PPD actually utilized constitutes merely an invitation to experiment without a reasonable expectation of success.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 25, 2008